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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	18

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/202,681	Applicant(s) MATHUR ET AL.	
	Examiner Richard G Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants amendment of claims 1, 2, 5, 10 and 11 in paper No: 17, filed 5/29/2001. Claims 1-12 are still at issue and are present for examination.

Applicants' arguments filed on 5/29/2001, paper No. 17, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 1-11 are objected to because of the following informalities: Newly amended claims 1, 2, 5 and 10 have added the recitation "; wherein the polynucleotide encodes a polypeptide having activity as a thermostable phosphatase." The "semicolon" that is recited here is unclear in light of the fact that each of the other portions of the claims are also separated by semi-colons. Based on this it is unclear if the above recitation should be included with part (c) or as an additional separate part of the claim, equivalent to parts (a), (b) and (c). If applicants intent is to separate each of the separate parts of the claims by semicolons, and applicants intent is that the above recitation belongs with part (c), it is suggested that a "comma" be used in the recitation rather than a semicolon. If applicants intent is otherwise, it is confusing how part (b) of claim 1, for example, can encode a thermostable phosphatase. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action.

Applicants amendment of the claims and their traversal of the rejection is acknowledged. Applicants submit that "the invention polynucleotides and enzymes are all required to have a structure/function relationship, that is the invention polynucleotides are required to encode, be complementary to, or hybridize with a polynucleotide that encodes a "thermostable phosphatase, or an enzymatically active fragment thereof". This argument is not persuasive because those polynucleotides which do not themselves **encode** a thermostable phosphatase, but merely hybridize to a polynucleotide which encodes a thermostable phosphatase, do not themselves have a defined function. While the limitation that they hybridize to specific polynucleotides may be sufficient for an adequate structural description of the claimed polynucleotides, their functional limitation remains undefined and therefore applicants have not described the structure/function relationship of the claimed polynucleotides. Further those polynucleotides which encode a "thermostable phosphatase" and are required to have 100% to 70% identity with the disclosed polynucleotide that encodes the protein of SEQ ID NO: 19, the polynucleotide having the sequence of SEQ ID NO: 28 are adequately

described such that one of skill in the art would consider that applicants were in possession of the claimed polynucleotides. Those polynucleotides which merely comprise 15 contiguous bases of such a polynucleotide (SEQ ID NO: 19 is 783 bp) or those enzymes which are required to comprise at least 30 contiguous amino acids of a 260 amino acid protein (SEQ ID NO: 28) are not considered to be adequately described with respect to structure.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enzymatically active proteins having the amino acid sequence at least 70% identical to SEQ ID NO: 28 or enzymatically active fragments thereof, as well as polynucleotides which encode these proteins, does not reasonably provide enablement for those proteins which merely comprise 30 amino acids of SEQ ID NO: 28 or the polynucleotides which encode said proteins.

The rejection is stated in the previous office action.

Applicants argue that those of skill in the art would not need to know the exact location in the polynucleotide or protein (of residues) that are "tolerant" to modification before any mutation or variant could be obtained. Applicants argue that they teach that various mutations can be readily made and the resultant polypeptides can be screened for phosphatase activity. This is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding a thermostable phosphatase) requires that one of ordinary skill in the art

know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without effecting phosphatase activity and thermostability; (B) the general tolerance of thermostable phosphatases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson, Ph.D.
August 13, 2001

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600